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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,797	08/19/2003	Richard G. Langlois	IL-11052	7465

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,797	LANGLOIS ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-50* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. 1-5, 12, 15, 16, 19, 27, 29, 31-50 are pending. Claims 41-50 have been withdrawn.

2. Claims 1-5, 12, 15, 16, 19, 27, 29, 31-40 are currently under examination.

Rejections Withdrawn

3. Applicant's arguments, see p.9, filed August 15, 2008, with respect to the rejection of claim 19 under 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive. The rejection of claim 19 under 35 U.S.C. 112, first paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 12, 15, 16, 27, 32, 33, 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470].

With respect to claim 1, Irving et al. teach a particle separation assembly for separating particles from a gas and collecting the particles within a liquid (column 3, lines 30-35), which would therefore be capable of separating selected potential bioagent particles from air, such as toxic microorganisms (abstract). Irving et al. further teach that the particle separation assembly

comprises a plurality of cyclone separation chambers and a liquid passage conduit connectable to the pump for delivering liquid to each cyclone separation chamber such that particles would be collected with the liquid by washing down the inner wall of each cyclone chambers and trapping the particles within the liquid (column 3, lines 40-58). This system would thereby constitute a wetted wall cyclone collector that would be capable of concentrating potential bioagent particles in a liquid. Irving et al. further teaches that the assembly may be used for a wide range of applications and can be integrated with a number of different biosensor or detector technologies (column 4, lines 5-20). Irving et al. do not specify that the biosensor or detector comprises a device for adding optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes, resulting in an array of beads having unique spectral addresses and coated with capture antibodies specific for a given antigen and potential bioagent particles that includes a flow cytometer with a laser unit for individually interrogating the microbeads.

Casey et al., however, teach a detection system for detecting microbial contamination involving lysing a cell suspension and extracting the DNA (para. 0314) and binding the DNA to probes comprising hapten recognizing intermediaries such as antibodies (para. 0065). The probes may be immobilized on optically encoded microparticles comprising polystyrene microspheres with two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256-0257). Casey et al. further teach that this would allow for multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256). Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual bead (para. 0022, 0269) for performing the multiplexed assays (para. 0269).

Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to for the detector integrated to the particle separation assembly of Irving et al. to comprise a flow cytometer and a unit for adding optically encoded microspheres comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence ., as suggested by Casey et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected.

With respect to the preamble, the recitation autonomous monitoring apparatus has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to automate the system of Irving et al. and Casey et al., since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

6. With respect to claim 2, Irving et al. also describes the particle separation assembly as an aerosol collector (column 3, lines 55-58).

7. With respect to claims 3-4, Irving et al. teach that the gas may comprise large interfering particles and small particles, and that the particle separator and collection assembly is capable of

removing the large interfering particles greater than 50 μm, and capture and concentrate particles less than 50 μm, which would include bioagent particles (column 1, lines 16-33).

8. With respect to claim 5, the cyclone collector taught by Irving comprises a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30).

9. With respect to claim 12, the detection system contains a lysing mechanism (para. 0314) which would be capable of lysing bioagent particles containing spores.

10. With respect to claims 15, 16, the cyclone collector taught by Irving may include a fluid collection port as well as a secondary injection port (column 10, lines 28-45), which would be capable of sequential injection as well as flow injection, and would therefore read upon the claims.

11. With respect to claim 27, Casey et al. teach polystyrene microspheres, as discussed above (para. 0257).

12. With respect to claims 32, Casey et al. teach PCR detectors for multiplex detection of analytes (see 0014, 0269).

13. With respect to claim 33, 35-37, Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual microsphere (para.

0022, 0269), wherein the detection means involves PCR amplification (para. 0014), and may be multiplexed (para. 0269) and in real-time (para. 0162-0166).

14. With respect to claims 38, 39, Casey et al. teach means for injecting a sample and adding PCR reagents, as well as for transporting to and from a PCR reactor in the form of pipettes (para. 0319), means for mixing the sample and reagent (para. 0317-319), and means for detecting the PCR amplified product involving gel electrophoresis (para. 00320). Irving et al. also disclose means for cleaning the conduits such as the inlets and cyclone separators of the particle separation assembly (column 12, lines 35-41), which would decontaminate and condition the conduits.

15. With respect to claim 40, Casey et al. teach that the microspheres may be suspended and resuspended (para. 0259).

16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Colston, Jr. et al. [US 2003/0032172].

With respect to claim 19, Irving et al. and Casey et al. teach the invention as discussed above, but fail to teach a super serpentine reactor to help prepare the sample.

Colston, Jr. et al., however, teach that mixers such as super serpentine reactors may be used to combine the sample and the PCR reagents (para. 0043). Therefore, one of ordinary skill in the art at the time of the invention, when presented with these two references, would have found it obvious to utilize the super serpentine reactor of Colston, Jr. et al. to perform the mixing of the reagents and PCR sample during the PCR preparation stage in the invention of Irving et al.

and Casey et al., in order to ensure a proper mixing of the PCR sample with the reagents so that accurate PCR amplification and analysis may be performed.

17. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Fisher et al. [US 6,897,031].

With respect to claim 29, Irving and Casey et al. teach the invention as discussed above. More specifically, Casey et al. teach a flow cytometer for used in a FACS-based method (para. 0022), but fail to teach that the flow cytometer comprises a red laser and a green laser.

Fisher et al., however, teaches a FACS machine for use in flow cytometry analysis (column 4, lines 47-55, 59-68), wherein multiple different lasers may each be used such that different measurements may be determined simultaneously from an individual particle (column 5, lines 48-65), wherein the lasers may be used to excite orange, red, green, and blue dyes (column 7, lines 65—column 8, lines 1-11), which would involve red and green lasers.

Therefore, one of ordinary skill in the art at the time of the invention would have found it obvious to have had multiple lasers, including a green laser and a red laser in the flow cytometer of Casey et al., in order to provide more flexibility in detecting multiple different parameters of the microspheres of Casey et al. simultaneously, allowing for more complex analysis to occur in a more rapid manner.

Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Miles et al. [US 6,576,459].

With respect to claims 31, 34, Irving et al. and Casey et al. teach the invention as discussed above, but fail to teach liquid based multiplexed immunoassay detectors.

Miles et al., however, teach both immunoassay and PCR detectors (see 46, 77 of the figure). More specifically, Miles et al teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would also be capable of functioning as a liquid array based multiplex immunoassay or PCR detector for analyzing infection agents and spores (column 2, lines 50-65), and which would be capable of analyzing optically encoded microbeads, such as those of Casey et al. (column 3, lines 25-41). Miles et al. also teach the use of Taqman assays (column 4, lines 60-65) which are quantitative PCR assays and which would require a PCR detector, and that the fluorescent signal is detected in real-time (column 4, lines 64-65).

Therefore, Miles et al. show that multiplexed immunoassay detectors and multiplexed PCR detectors are equivalent structures known in the art. Therefore, because these two types of detectors were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a multiplexed immunoassay detector for a PCR detector

Response to Arguments

18. Applicant's arguments with respect to claims 1-5, 12, 15-16, 19, 27, 29, 31-40 have been considered but are moot in view of the new ground(s) of rejection. The limitations to which each

reference teaches and which applicants claims that the prior references did not teach has been specifically addressed in the above rejections.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner
Art Unit 1641